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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,139	08/08/2001	Rosanne M. Crooke	ISPH-0596	3066

7590 11/20/2002
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EXAMINER
SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,139

Applicant(s)

CROOKE ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Response to Arguments

1. Applicant's response filed September 4, 2002 has been considered. Rejections and/or objections not reiterated from the previous office action mailed May 4, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. Arguments regarding claims 11 and 15-20 are noted but not considered in light of the cancellation or amendment of said claims.

Applicant's arguments with respect to claims 1, 2, and 4-14 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 2, and 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al., or Drayna et al., in view of Bennett et al.

The invention of the above claims is drawn to antisense compounds, their internucleoside, sugar, nucleobase, and 2' modifications, chimeras, and compositions comprising said compounds and pharmaceutically acceptable diluents or colloidal dispersion systems thereof that target and inhibit the expression of human cholesteryl ester transfer protein.

Liu et al. teach an antisense compound with phosphorothioate modifications that hybridizes with and inhibits the expression of human cholesteryl ester transfer protein. Liu does not teach sugar, nucleobase, and 2' modifications, chimeras, and compositions comprising said compounds and pharmaceutically acceptable diluents or colloidal dispersion systems thereof.

Drayna et al., teach the cDNA sequence encoding human cholesteryl ester transfer protein.

Bennett et al. teach how to inhibit specific mRNA transcripts using antisense compounds that target the 5'-untranslated region, the start codon region, the stop codon region, or the 3'-untranslated region of said transcript, and also teach modifications of antisense compounds comprising sugar, nucleobase, 2' modifications, chimeras, and pharmaceutical preparations.

It would have been obvious to one of ordinary skill in the art to make and use antisense oligos targeting the 5'-untranslated region, the start codon region, the stop codon region, or the 3'-untranslated region of human cholesteryl ester transfer protein. It also would have been obvious to one of ordinary skill in the art to incorporate modifications as taught by Bennett et al. into either the antisense compound of Liu et al., or into antisense oligonucleotides designed from the complementary sequence of human cholesteryl ester transfer protein as taught by Drayna et al. One of ordinary skill would have been motivated to make such compounds, because Liu et

al. teach that inhibiting human cholesteryl ester transfer protein may counteract atherosclerosis, and Drayna et al. teach that said protein plays an important role in pathological cholesterol homeostasis. Further, because Liu et al. teach modified phosphorothioate oligos, and because Bennett et al. teach that such modifications increase an antisense compound's cellular uptake, target affinity resistance to degradation and bioactivity, one would have been motivated to create such compounds. Finally, one would have a reasonable expectation of success of making said modified oligos, given that successful use of modified antisense-oligos against human cholesteryl ester transfer protein was previously demonstrated by Liu et al., and because the modifications of Liu et al. and Bennett et al. are easily performed by one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
November 15, 2002



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600